



August 15, 2005

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Notification of statements on Dietary Supplement Labels

Division of Compliance and Enforcement
Office of Nutritional Products, Labeling and Dietary Supplements
Food and Drug Administration
(HFS-810)
5100 Paint Branch Parkway
College Park, MD 20740-3835

AUG 24 2005

Dear Sir/Madam:

Reference is made to PFO-Pure Cod Liver Oil, marketed by Arkopharma, LLC.

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, as codified in 21 U.S.C. 343(r)(6), notification is submitted for structure/function statements made on the following dietary supplement product.

Product Name: Health From The Sea – PFO-Pure Cod Liver Oil

Ingredients: Cod Liver Oil, Vitamin A & D, EPA, DHA

Company Name/ Address: Arkopharma, LLC
19A Crosby Drive
Suite 300
Bedford, MA 01730-1401

Text of Claims:

1. Each serving of PFO-Pure Cod Liver Oil supplies 80% of the recommended Daily Value for Vitamin A and 100% for Vitamin D, plus omega-3 EPA and DHA, all to support a healthy immune system.
2. Health From The Sea PFO™ Pure Cod Liver Oil – Omega-3 Immunity for all Ages.
3. Omega-3 Healthy Immune Support

In accordance with 21 CFR 101.93, the disclaimer statement is bolded and boxed on all panels of the label where structure/function claims appear.

The undersigned certifies that the information contained in this notice is complete and accurate and that Arkopharma, LLC, has substantiation that the statements are truthful and not misleading.

As required, the original and two copies of this notification are enclosed. If you have any questions regarding this information, please contact the undersigned at (781) 276-0505.

Sincerely,

Barbara Levenstein

Barbara Levenstein, M.S.
Director of New Product Development
Arkopharma, LLC

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ARKOPHARMA, LLC dba HEALTH FROM THE SUN

SALES, MARKETING & FINANCE OFFICE

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WAREHOUSE & DISTRIBUTION CENTER

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